Clarification meeting – Members of the European Parliament, EFSA, Secrets Toxiques
June 11th, 2021 – Co-Chairs : Mr. Claude Gruffat and Mr Guilhem de Seze
Minutes – English version

Attendees:

Mr. Claude Gruffat, MEP, session's president

Mr. Benoît Biteau, MEP

Pr. Gilles-Eric Seralini, first author of the study « Toxic compounds in herbicides without glyphosate »

Mr. Gérald Jungers, second author of the study « Toxic compounds in herbicides without glyphosate »

Mr. Philippe Piard, co-president of the NGO Secrets Toxiques

Mr. François Veillerette, board member of the NGO Secrets Toxiques

Mrs. Océane Mariel, APA for Mr. Benoit Biteau, MEP

Mrs. Merry Laballe, APA for Mr. Eric Andrieu, MEP

Mr. Lucas Trottmann, APA for Mr. Manuel Bompard, MEP

Mr. Charles-Maxence Layet, APA for Mrs. Michèle Rivasi, MEP

Mr. Jacques Loyau, APA for Mr. Claude Gruffat

Mr. Axel Singhofen, political advisor

Mr. Emmannuel Kujawski, political advisor

Dr. Andy Battentier, campaign manager, Secrets Toxiques

Dr. Guilhem de Seze, head of "Scientific Evaluation of Regulated Products" Department (REPRO) and session's co-chair

Dr. Juliane Kleiner, ad interim head of "Risk Assessment and Scientific Assistance" Department (RASA)

Dr. Suzanne Hougaard Bennekou, DTU (Denmark)

Dr. Tamara Coja, AGES (Austria)

Dr. Thorhallur Halldorsson, University of Iceland

Mrs. Manuela Tiramani, head of "Pesticide Peer Review" unit (PREV)

Mr. Chris Lythgo, team leader chemistry and environmental exposure (PREV)

Mrs. Mathilde Colas, team scientific coordination and administrative support (PREV)

Mrs. Victoria Villamar, head of Engagement and Cooperation unit (ENCO)

Mr. Christophe Wolff, institutional affairs (ENCO)

Mr. Flavio Fergnani, institutional affairs (ENCO)

Excused:

- Mrs. Michèle Rivasi, MEP
- Mr. Manuel Bompard, MEP
- Mr. Eric Andrieu, MEP

Minutes

Claude Gruffat thanks the participants and reminds this meeting's context. It was initiated by a letter addressed to EFSA by 63 MEPs and 56 French MPs on February, 25, 2021. This letter invited to apply the Regulation (EC) No 1107/2009 on market authorisation of PPPs, and the decision of the Court of Justice of the European Union of October 1st, 2019. EFSA answered on March 31st, 2021. Today's meeting follows MEP's demands of clarification on missing elements in EFSA's answer. EFSA's services, the five MEPs that initiated the letter of February 25th, and the experts of the Campaign "Secrets Toxiques" are invited to this meeting. Claude Gruffat introduces his delegation and gives the floor to Guilhem de Seze.

Guilhem de Sèze welcomes this follow-up meeting which was suggested in EFSA's letter of March 31st and welcomes the representatives of the European Parliament. He mentions the work of the PEST Commission from the last parliamentary term on the topic of pesticides. For EFSA, this meeting is inscribed in the continuity of this dialogue with MEPs. He reminds that for other stakeholders, such as NGOs and scientists, other contexts exist to meet EFSA. Today's meeting is for EFSA a dialogue with the MEPs, even though EFSA is happy to welcome the whole delegation. He reminds that this meeting is recorded and will be available on EFSA's website, according to EFSA's aim of transparency with all stakeholders and citizens. He introduces himself and members of EFSA's staff and let EFSA's experts introduce themselves.

Claude Gruffat reminds the meeting's organization. A document structured in 19 questions has been transmitted to EFSA a few weeks ago. These questions are the ones that still need to be answered despite EFSA's letter of March 31st. An amended version, which includes two additional questions, was sent on 9 June 2021. These questions are numbered and classified into 6 themes. They will be asked one after the other. Claude Gruffat will ask the questions, then EFSA will answer them, and the "Secrets Toxiques" can ask some follow-ups. Océane Mariel is in charge of taking the minutes of the meeting in French. Andy Battentier is in charge of the minutes in English. In the end of each question, Océane Mariel will proceed to a short summary of the answers. The minutes in French and in English will be addressed to EFSA for validation.

Introduction

In its decision from October 1st, 2019, the CJEU reiterates that the legislator sought that the precautionary principle written in EU's treaties is fully integrated in Regulation (EC) No 1107/2009 on market authorisation of PPPs, in order to ensure a high level of protection for human health.

This concern of public health justifies that we bring today to EFSA's attention questions on its responsibility in the application of the legislation on pesticides.

Part 1, EFSA's evaluation in the case of glyphosate

In its decision of October 1st, 2019, the CJEU declares that "the procedures leading to the authorisation of a plant protection product must necessarily include an assessment not only of the specific effects of the active substances contained in that product, but also of the cumulative effects of those substances and their effects combined with other constituents of that product".
The Court also specifies that the process of approval of active substances requires an evaluation of the effects of the various components of a product. This is required not only for the Member State receiving an application but also for the European Authority (EFSA), including when EFSA adopts its conclusions (given the current state of scientific and technical knowledge), defining whether an active substance meets the approval criteria.

1st question: In your letter of March 31st, you mention your study of representative formulations. Where are the raw data of long-term toxicity tests of the formulations that you study, among the products without glyphosate that you have authorised? Data on health and environment cannot be covered by industrial secrecy laws, can you publish a link for these data?

Guilhem de Seze answers this first question and specifies that EFSA does not authorise the active substances. It gives scientific opinions to risk managers, in this case the European Commission and Member States, for them to take the decision upon authorising or not active substances..
Active substances are authorised by the European Commission through the comitology process with Member States.
Member States authorize the formulated products.
Both the European Commission and Member States take their decision accounting for EFSA's scientific opinion.

The raw data used to evaluate the toxicity of active substances and representative formulations are in the dossiers provided by applicants. These data are available to EFSA, Member States, and the European Commission.
The current regulation forbids EFSA to publish the raw data and original study reports. Instead, EFSA publishes summaries of the studies.
However, these raw data can be requested under Regulation (EC) No 1049/2001, concerning public access to European Parliament, Council and Commission.
Since March 27th, 2021, the new "transparency" Regulation (EU) No 1381/2019 gives a mandate to EFSA to publish the raw data used to prepare its scientific opinions, for all dossiers submitted after the entry into force of the Regulation.
Nevertheless, this new Regulation is not retroactive, and therefore the raw data concerning the active substances and formulation of the products analysed by the Seralini and Jungers study[1] can only be requested through the process described by Regulation (EC) 1049/2001.

Gilles-Eric Seralini outlines that the « active substance », whose toxicity is evaluated by EFSA, is declared as such by the applicant, who provides the long-term toxicity analysis

[1] SERALINI G-E., JUNGERS J., "Toxic compounds in herbicides without glyphosate", *Food and Chemical Toxicology*, Volume 146, 2020, https://doi.org/10.1016/j.fct.2020.111770

evaluated by EFSA. He asks if EFSA is aware of long-term toxicity tests, i.e. more than one year on mammals, of the new formulations without glyphosate studied in his paper. He specifies that his questions is about the whole commercial mixture and not the declared active substance.

Guilhem de Seze answers that the risk assessment of pesticides formulations, and the decision to authorise them is the field of competence of Member States

Gilles-Eric Seralini disagrees and specifies that the decision of the Court of Justice of the European Union says clearly that the risk evaluation of pesticides formulations is also in EFSA's field of competence.

Guilhem de Seze says that the data on all envisaged or existing formulations is not provided to EFSA under the current regulation. Therefore, the risk assessment on formulations cannot be performed.

Gilles-Eric Seralini disagrees that the current regulation gives only to Member States the competence to evaluate the toxicity of formulations.

Guilhem de Seze invites to ask to Member States how formulations are evaluated. He clarifies that these formulations are composed of an active substance evaluated in a peer-review process by EFSA, and co-formulants evaluated in other regulatory frameworks. He cites the importance of the REACH Regulation (EC) No 1907/2006 and ECHA, the European Chemicals Agency in Helsinki, which impose a risk assessment to all chemicals producers before market authorisation. Data on co-formulants are therefore available under REACH regulation, which is not in the field of competence of EFSA.

Gérald Jungers remarks that EFSA authorises products on the market with partial data.

Guilhem de Seze reiterates that EFSA does not authorise any substance, but evaluates risks on the basis of the data provided, and on the publicly available scientific literature. Once this risk is evaluated, EFSA gives a scientific opinion to the risk managers who take the decision to authorise or not the active substance.
He indicates that Member States have the responsibility to evaluate the formulations. He precises that the reason for this is that many formulations are possible starting from an active substance, and that these formulations need to be adapted to several national factors, such as the type of crops, climatic and geographic conditions of Member States. This is why the competence of formulation's evaluation is attributed to Member States. He asks Manuela Tiramani to give more elements on the peer-review system coordinated by EFSA.

Manuela Tiramani says that EFSA evaluates all the data that is provided.
About representative formulations: for a new authorisation or for renewal on the market, at least one representative formulation has to be submitted in the applicant's dossier. The information assessed by EFSA is submitted by the applicant, according to the legal data requirements.
She says that currently, no data requirements exist for long term toxicity to mammals and humans.

EFSA assesses data on the active substance, co-formulants and impurities taken in isolation. In its assessment, it highlights concerns, data gaps, and possibly concludes on the safety. Then it provides its opinion to risk managers: the European Commission and Member States. What she describes is the dual system in Europe, consisting in EFSA doing the first step, analysing the toxicity of the active substance, and at least one representative formulation. Then, at the national level, Member States authorise applications for formulations, with at the basis the active substance authorised by the European Commission informed by EFSA's opinion.

Axel Singhofen says that according to his information, Member States only evaluate acute toxicity. He asks whether, practically, no long-term toxicity evaluation is performed on representative formulation, other than the one analysed by EFSA, in the dual system described by Manuela Tiramani.

Tamara Coja answers that under Regulation (EU) 284/2013, the data requirement specifies only that acute effects in regard to human health have to be addressed for any kind of formulation.
At national level, a deep look is nonetheless performed in the available information on the isolated effects of co-formulants, synergists and safeners. Co-formulants are chemicals registered under REACHandsafeners and synergists are compounds that fall under the pesticides regulation.
Members States rely on information on co-formulants provided under REACH. Neither EFSA nor Member States have access to additional data on co-formulants, they rely on what is available through REACH regulation.
She concludes that this scattered regulatory framework is certainly something that should be brought to the attention of the legislator.

Axel Singhofen reformulates the answer of Tamara Coja : EFSA evaluates the toxicity of one representative formulation, and then Member States authorise all the formulations. But Member States only looks at parts of the formulation (active substance and information on co-formulants) and do not test the formulation as a whole. He asks if this is correct.

Tamara Coja answers that it is not completely like this although it is going quite in this direction. The data requirements specified in Regulation (EU) No 284/2013 are related to acute toxicity, irritation properties, and skin sensitisation. Data under REACH can be limited or with a very high data package, but are used by Member States to evaluate the isolated effects of co-formulants.

Claude Gruffat does the remark that the level of complexity of the system of authorisation of pesticides on the market is such that many flaws are present, and that the protection of consumers and citizens does not seem ensured.

Guilhem de Seze says that Claude Gruffat's remark echoes the conclusions of the PEST committee report of 2018, which stated that the European evaluation system of the toxicity of pesticides was one of the most robust worldwide, but that there was room for improvement.

2nd question: What are the in vivo tests performed or authorised by EFSA to validate the representative formulation of pesticides in Europe?

Manuela Tiramani answers that neither Member States nor EFSA perform any in vivo or in vitro experimental tests, whether on the formulation or the active substance.
Performing these tests is the responsibility of applicants who are looking for renewal of approval of a substance already existing on the market, or for authorization of a new one. For this, they have to prepare a dossier according to data requirements as specified by the law. The data provided in this dossier, including thorough scientific literature assessment, are the one assessed by EFSA.

Gilles-Eric Seralini precises that it is EFSA's legal responsibility to hold its opinion if it does not have access to all data. He also specifies that compounds such as benzo(A)pyren and arsenic can be found in formulations. The effect of these compounds and their effect in formulation cannot be assessed by EFSA, as it does not perform in vivo long-term toxicity evaluations. He asks if EFSA assesses in vivo long-term toxicity evaluation.

Manuela Tiramani precises that the requirements on the formulation are mainly for mammalian acute toxicity through oral, dermal and inhalation exposure, as well as skin and eye irritation and skin sensitisation. Other requirements exist for the effect on the environment. However, the purpose of EFSA's peer-review assessment is to evaluate the active substance according to the dual process approach.

Gilles-Eric Seralini concludes that no long-term evaluation of the formulations' toxicity is performed on mammals before market approval.

Guilhem de Seze provides additional clarifications on the data available on long-term toxicity. He cites the data required from the applicant under the regulation 284/2013, including the data on formulations that will be reviewed by Member States. Besides, toxicity data on co-formulants taken in isolation are required from industrial chemicals under other EU regulations, specifically REACH regulation. Hence, these regulations have to be consulted to know which data are required.
He says that EFSA does not verifies which data is available under REACH, or commercial formulations because tjeir evaluation is the responsibility of Member States, which look at available data required in the law and scientific literature when they evaluate the final products.

Gilles-Eric Seralini reminds that the decision of the Court of Justice of the European Union specifies that the evaluation of commercial formulation is also EFSA's responsibility

Guilhem de Seze agrees that it is the case for representative formulations. Their analysis is performed by EFSA, using the data provided by the applicants, the one available through other regulations such as REACH, and scientific literature.

Gilles-Eric Seralini remarks that such data cannot be found in scientific literature when herbicides are new products.

Guilhem de Seze says that no source of data is excluded by EFSA.

3rd question: What is considered as a representative formulation and how is it verified?

Christopher Lythgo explains that applicants have to include at least one representative formulation in the submitted dossier. The regulation specifies that the intended use of this formulation should reflect the way the active substance can be effective.

Each formulation is related to specific intended uses, which include, amongst others, factors such as the crops target of the application, the application methods, the seasons and number of applications, as well as the application rates.

Member States can authorise more application methods and diversity in formulation types than those proposed in the application for EU level approval. EFSA considers only the proposed representative formulation as included in the EU dossier.

The definition of the representativeness of a formulation can be found in article 8.1 of Regulation (EC) No 1107/2009. The use should be representative for a wide grown crop in a specified zone. Three zones are defined by the regulation. If the information provided does not cover all zones or concerns a crop which might not be widely grown then the applicant has to provide justification for this.

The applicant selects the representative formulation that he puts in the dossier for EU approval, and that EFSA assesses.

Axel Singhofen asks how EFSA ensures that the representative formulation presented by the applicant is representative of the co-formulants currently used, and that the applicant does not send to EFSA a formulation that contains above all benign co-formulants.

Tamara Coja answers that in any case, all formulations will be assessed by Member States according to Regulation (EC) No 284/2013.

Axel Singhofen reminds that EFSA's experts specified that Member States look at data on co-formulants and certain acute effects of the formulations, mirroring what EFSA does for the representative formulation it is provided with.

Tamara Coja says that EFSA and Member States indeed have the same approach, which is to analyse the data they are provided with under current regulation.

Guilhem de Seze specifies that the formulation is representative in the sense that it allows to study the risk of the active substance in a scenario of real use.

He also specifies that such scenario of real use is obviously difficult to assess for a new active substance not yet on the market, but the applicant indicates how the active substance will be used in a formulation. In this case the representative formulation is the first formulation that the applicant intends to produce with the active substance.

For authorisation renewal, the representative formulation needs to be a real formulation, existing on the market. The evaluation of "how representative" this representative formulation really is falls under the responsibility of Member States. He summarises the process as such: the Rapporteur Member State receives the dossier, the rapporteur Member State decides to accept or not the representative formulation, and EFSA works on this representative formulation.

Manuela Tiramani precises that the list of unacceptable co-formulants in plant protection products was published by the European Commission in the annex 3 of Regulation (EC) No 1107/2009.
All the data provided to EFSA is analysed. In case data are missing or unclear, questions will be asked with regard to co-formulants or, more generally, clarification on possible toxicity properties.
The list of unacceptable co-formulants serves as a reference.

Guilhem de Seze summarises that the legislator decides which co-formulants cannot be included in the composition of a pesticide product.

Gilles-Eric Seralini says that EFSA only analyses declared substances, and not the whole of the formulation products.

Guilhem de Seze asks whether Gilles-Eric Seralini may be referring to fraud, as there can be no undeclared constituents in a pesticide active substance or a pesticide formulation.

Gilles-Eric Seralini confirms that there are undeclared substances, as specified in the scientific literature. EFSA just work on the data it is provided with, but does not have the data on all products of formulation, and does not evaluate the long-term effects of the formulation. He asks if EFSA considers that this aspect has to be improved.

Guilhem de Seze reminds that the evaluation of formulations is the responsibility of Member States. The formulation, i.e. the pesticide product, which is going to enter into the market, is evaluated and the decision on its authorisation is with the Member states. For the other question, if there are non-authorised substances included in the composition of a pesticide product, this is called a fraud..
He suggests that Gilles-Eric Seralini may be referring to impurities.

Gilles-Eric Seralini contests the notion of impurities, as from a scientific point of view co-formulants, synergists, impurities are all chemical compounds of the formulation.

Guilhem de Seze outlines the importance of sticking to legal terminology, as confusion could arise if the technical vocabulary is not used in a shared way.

Gilles-Eric Seralini specifies that substances are called “co-formulants”, “synergists”, or “impurities” by industrials, and that EFSA cannot verify whether a substance is an actual co-formulant, active substance or impurity.
He takes the example of benzo(A)pyren, saying that EFSA cannot know if the active substance is glyphosate of benzo(A)pyren that would be in the final product by chance, fraud, negligence, or because of the production process. He asks Guilhem de Seze to confirm that the definition of active substance, synergist or co-formulant is provided by applicants.

Guilhem de Seze says that benzo(A)pyren is a carcinogenic substance forbidden to be added in any consumer product or in pesticides. He says that nobody would put intentionally benzo(A)pyren in a pesticide formulation, that it will never be authorised as an active substance and if someone would try to obtain such authorisation, the dossier would not pass the step of the rapporteur Member State.

He concludes that Gilles-Eric Seralini mentions impurities, which are part of the dossier and are evaluated by EFSA.

Gérald Jungers says that benzo(A)pyren was found in most products of the Seralini and Jungers study. He asks whether EFSA questions market authorisation and applies precautionary principle when studies like this one are published, finding arsenic and carcinogenic substances in authorised products.

Guilhem de Seze says that an applicant asking for an authorisation has to provide data according to the law, which includes data on the degree of purity of substances and nature of impurities. Using these data, Member States can control these impurities in the commercial product that they authorise.

Philippe Piard remarks that when members of EFSA's experts mention co-formulants, they mention them as substances studied separately. He says how an authorisation can be given on a formulation, when no data is available on the mixture of its formulants.

Thorallur Halldorsson says that the last few years have seen a rapid development of standard methodologies to deal with chemical risk assessment for chemical mixtures.

Axel Singhofen reiterates the question on whether a mixture assessment exists. He recalls that regulation on pesticides was issued in 2009, which states that additive and synergistic effects have to be considered with methods approved by EFSA. He asks if methods have been developed or are under development, or if in 2021 no methods are approved by EFSA.

Thorhallur Halldorsson says that for chemical risk assessment, either for a single compound or multiple compounds, standard procedures are needed. These procedures have to be agreed upon and scientifically sound. Development is ongoing, but no method has been established so far.

Guilhem de Seze says that the draft guidance on mixture assessment was adopted by the Scientific Committee of EFSA in April this year and should be adopted in autumn 2021. This is a first step for the adoption of a standard methodology.

Thorhallur Halldorsson says that EFSA is ahead of many other international agencies on this topic.

Gilles-Eric Seralini says that these methodologies exist since years, consisting in in vivo test and also omics. These methods are used by all scientists in the world.

Thorhallur Halldorsson says that an infinite number of chemical mixtures can be made with a few samples of ingredients, which is why agreed methods and protocols are needed to assess mixtures, in order to avoid problems associated with doing chemical risk assessment improperly.

Gilles-Eric Seralini says that the formulations are available, and that they are the final chemical mixture.

Benoît Biteau considers that a clear evaluation of the product as commercialised on the market is needed, and not only of the individual molecules composing it. It is probably where answers need to be brought, on the objective, rigorous and effective evaluation of the hazards of a product placed on the market.

Guilhem de Seze remarks that starting from an active substance, hundreds, even thousands of formulations can be made. It is therefore not possible to test every formulation, which is the competence of Member States in any case.

Gilles-Eric Seralini says that thus they should not be authorised.

Guilhem de Seze points to the time necessary for carrying out those studies, and points to the issue of animal welfare, calling for considering the amount of animal testing required.
By testing components one by one, toxicity problems are very often detected.
EFSA has worked on the combined effect of substances, whether in mixtures or when they are present in the environment in the last 10 years. In 2019, a first guidance document on mixture evaluation was published. A second document is currently under finalisation and should be published in September.
This second document will give a basis to perform the evaluation of cumulative effects of mixed chemical compounds, for pesticides and other food safety concerns.
He outlines the complexity of these questions, and that EFSA is one of the most advanced safety agencies in developping methodologies on these questions.
An international workshop is planned for October this year. If some agencies are more advanced than EFSA on these topics, they will be invited to share their knowledge.
These methodologies are just starting to be used for regulatory purposes.

Gilles-Eric Seralini disagrees and outlines that methodologies for mixtures assessment exist, and that EFSA does not take the initiative not to authorize the products for which no sound analysis is available.

Claude Gruffat follows the remark of Benoît Biteau and considers that an evaluation molecule by molecule, which allows the pesticide producer to put the molecule in the mixture he wants, is not the way the evaluation should work in the future. Indeed, it put citizens at risk as it leads to situations of exposure where the risk is not adequately evaluated.

4th question: In case of a contradiction between data provided by applicants and data available in scientific literature, which are the data on which EFSA builds its opinion on the toxicity of representative formulations?

Suzanne Bennekou indicates that according to the Regulation, the applicant is obliged to collect all the data which would be relevant for the assessment, both for the active substance and the representative formulation. Apart from the studies included by law in the dossier, it is mandatory to also consider the scientific literature. Evidence is appraised for its reliability and relevance regarding the question that the legislation sets out. All lines of evidence are weighted according to its reliability and strength. All evidence is assessed, and nothing is discarded.

5th question: Why EFSA discards publications focusing on complete, commercialized products? For instance, for glyphosate, EFSA explains that discarding these articles explain the difference between its conclusions and the ones of the IARC? Is EFSA aware that discarding these studies is contrary to EU regulation and the decision of CJEU?

Thorhallur Halldorsson indicates that EFSA does not reject any publication a priori. Assessing scientific literature is often complex as its design often does not allow the regulatory experts to clearly identify the formulated products, the batch used in the experiment and so on. As a result, it is often not possible to attribute the observed effect to certain chemicals that comes in the formulation. Many scientific publications are not conducted in a way that is intended to be part of a risk assessment process.

Axel Singhofen asks to clarify why EFSAsays on one hand that EFSA is not discarding anything, while EFSA said earlier in the meeting that EFSA did not look at the data with regard to the formulations as a whole.

Manuela Tiramani explains that the Rapporteur Member State produces a draft assessment report, which is a sort of a high level scientific summary of the dossier provided by the applicant. This report is carefully checked, by EFSA and Member States during the peer-review.
EFSA's focus, however, is on the active substance. The information from other publications helps to clarify the potential of the active substance to create any concern.
For instance in the case of glyphosate, EFSA highlighted and assessed the concerning role of tallowamine.

Guilhem de Seze says that tallowamine is a good example, showing how the evaluation of representative formulations is done according to the regulations. The regulations ask to check all available data. If new information is found in some studies available in public scientific literature, it is analyzed and included in EFSA's scientific opinion, to be brought to the attention of risk managers. In the case of glyphosate, this process led to the ban of tallowamine.

Axel Singhofen asks if in the case of tallowamine, the evaluation was considering tallowamine alone or in combination with glyphosate.

Manuela Tiramani indicates that the peer review of glyphosate was aimed at clarifying the toxicological potential of glyphosate only. The dual approach consists in EFSA addressing the active substance first.
However, given the new information provided, EFSA went further assessed the role of tallowamine per se, concluded that tallowamine should not be used, and highlighted the risk to risk managers.

Axel Singhofen asks if this means that synergists, in the current system, are only assessed in their own right and not in their function as a synergist where they could have an effect together with the other substances.

Manuela Tiramani indicates that to define the relevance of an impurity, EFSA assesses whether the impurity has on its own a toxicological profile that would add either a different toxicological profile to the active, or a higher potency effect.
If so, EFSA highlights this fact in its conclusions and point the impurity as a subject of concern.
In principle, EFSA assesses the formulation insofar as it clarifies the use of the active substance in a certain number of representative uses.
If EFSA spots that a component has a synergistic role, or even antagonistic or additive effect, it reports it in its conclusions. In the end, if EFSA concludes that data is missing, it results in data gaps for the managers to consider.

Gilles-Eric Seralini indicates that tallowamines are not only a class of synergists and can have a herbicidal effect of their own. He showed in 2014, 2015, 2017, 2018 that tallowamines were much more toxic on human cells in formulations with glyphosate than glyphosate alone. EFSA did not used these works, but it led to a ban in France on formulations containing tallowamines and POEAs.
He explains that at the beginning, the problem came from the fact that EFSA accepts as true what applicants said on active substances, synergists and formulants.
He considers that it is not necessary to authorise the current diversity of available formulations, and that one or two would be sufficient. The 15 formulations studied in the Seralini and Jungers paper are all very different in the formulation compounds.
He asks if EFSA considers that the representative formula which long-term effects have been assessed should be the only one authorised.

Guilhem de Seze asks for clarification of the question.

Gilles-Eric Seralini says that EFSA has the authority to demand long-term toxicology tests of the representative formulation to the applicants. He asks if EFSA intends to do this with the new regulation on transparency.
About animal welfare, he remarks that it is ethically problematic to give these products to billions of humans and animals, and that it is better to test them on dozens or hundreds of mammals before giving them to billions.
He asks if EFSA could only authorise one representative formulation, at the EU level and Member States level, whose toxicity would be evaluated on the long term, on mammals.

Guilhem de Seze says again that EFSA does not authorise neither formulations nor active substances.

Gilles-Eric Seralini answers that the European Commission generally follows EFSA's opinions.

Manuela Tiramani says that, during and at the end of the peer review process,EFSA highlights data gaps, issues that could not be finalised and critical areas of concern, which is what is missing to allow a robust risk assessment. This information is then given to risk managers.
EFSA is also trying to reduce the use of in vivo studies for animal welfare purposes, and is taking into account the use of alternative methodologies.

Guilhem de Seze says that such questions are for the legislator, and that EFSA is here to answer the questions and considerations on how it applies the current legislation. He says that EFSA works with the data as stipulated by the Regulation.

Gilles-Eric Seralini remarks that Manuela Tiramani just said that EFSA could ask for more data.

Guilhem de Seze confirms that this is the case in some instance, under the current Regulation[2].

Part 2. Reexamination of approvals and authorisations in the case of glyphosate

A market authorisation can be removed at any time, in function of the evolution of knowledge on the risks presented by a product already commercialised. The presentation of studies and scientific proofs showing the dangerous nature of a product can lead EFSA to intervene and produce a negative opinion to the pursuit of the use of a product already commercialised.

6th question: The Seralini and Jungers study focused on all herbicides without glyphosate for consumers. What are the differences between the toxicity analysis of representative formulations authorised by EFSA and the formulations determined by the study?

Christopher Lythgo remarks that one of the active substances studied by Seralini and Jungers in their article, Benzalkonium Chloride is not authorised as an herbicide in the EU. It is currently listed as a surface biocide. Therefore EFSA has not assessed any representative product containing this substance.It is illegal to sell it as a herbicide.
For one of the three active substances, EFSA found levels of lead and iron in levels comparable to what was found by Seralini and Jungers. They were understood as being impurities resulting from the production process. The lack of data about their presence was highlighted as data gap.
For the two other active substances, the elements presented in the Seralini and Jungers study were not found in the in the active substance dossier. Where data was missing, EFSA highlighted the data gap and informed risk managers that more information was needed on the impurity profiles and the constituents of these products.

Gilles-Eric Seralini asks if the same results were found concerning polycyclic aromatic hydrocarbons

Manuela Tiramani confirms that lead and iron were the only impurities that were found in the dossier for one active substance out of the three analysed in the paper by Seralini and Jungers. (the fourth active substance analysed by Seralini and Jungers is not a pesticides active substance)..

[2] EFSA adds as *post-scriptum*: However the available regulatory timeframe does not allow to ask for more than a few clarifications; this is why any remaining data gaps are reported in the conclusion of the peer review

Guilhem de Seze says that polycyclic aromatic hydrocarbons are not in the data set submitted to EFSA and specifies that this is visible in the conclusions that EFSA published. It is possible to access and look what information has been declared, submitted and evaluated by EFSA.

Manuela Tiramani says that the data available on the two other active substances do not show any of the impurities of concern highlighted in the paper.

Gilles-Eric Seralini says that it is EFSA's responsibility to qualify compounds as impurities. He asks if EFSA will order further analysis with these carcinogens in the representative formulations or in the formulations that EFSA has access to, for these herbicides.

Manuela Tiramani says that EFSA does not have the right to order further analysis.

Gilles-Eric Seralini asks if they will request them

Manuela Tiramani says that EFSA cannot request data either, but that it can only highlight the gaps at the end of the process. From this point, it is up to the risks managers to decide if they authorise the substance as such, or if they want to go back to the applicant for confirmatory information.

Claude Gruffat concludes this meeting as the end time has been reached. He thanks the participants and proposes to continue this exchange during another session, if possible in a close future.

Guilhem de Seze thanks the participants for this dialogue, which according to him showed the need to explain how the legislation works and how EFSA applies it. He reminds the possibilities for stakeholders to dialogue with EFSA through its established stakeholders engagement mechanisms.